

CLAIMS:

1. A process for obtaining human monoclonal antibodies (hMoAb) capable of binding to Hepatitis B virus surface antigen (HBVsAg) comprising:
 - (a) immunizing a chimeric rodent M4 having xenogeneic hematopoietic cells with Hepatitis B surface antigen HBVsAg such that xenogeneic antibody-producing cells are produced in said rodent, wherein said rodent M4 is a rodent M1, the hematopoietic cells of which have been substantially destroyed, said rodent M1 having transplanted therein hematopoietic cells derived from a mouse M2 having a hematopoietic deficiency, and xenogeneic hematopoietic cells derived from human M3;
 - (b) removing and immortalizing said antibody-producing cells;
 - (c) selecting and cloning the immortalized antibody producing cells producing the antibodies capable of binding to HBVsAg and;
 - (d) isolating the antibodies produced by the selected, cloned immortalized antibody producing cells.
2. A process according to Claim 1, wherein the rodent M1 is a BALB/C mouse and the mouse M2 is a SCID mouse.
3. A process according to Claim 1 or 2, wherein the human M3 is human having a high level of anti HBVsAg antibody and said xenogeneic hematopoietic cells derived from human M3 are peripheral blood lymphocytes (PBL).
4. A process according to Claims 1-3, wherein the Hepatitis B surface antigen is Engerix™-B vaccine.
5. A human monoclonal antibody being selected from the group consisting of:
 - (a) the monoclonal antibody 18.5.1013 which is secreted by the hybridoma cell line deposited in the European Collection of Cell Cultures (ECACC) under Accession No. 96052170; and
 - (b) fragments of the antibody of (a) which substantially retain the antigen binding characteristics of the whole antibody.
10. A human monoclonal antibody being selected from the group consisting of:
 - (a) the monoclonal antibody 19.79.5 which is secreted by the

hybridoma cell line deposited in the European Collection of Cell Cultures (ECACC) under Accession No. 96052168; and

(b) fragments of the antibody of (a) which substantially retain the antigen binding characteristics of the whole antibody.

11. The hybridoma cell line deposited at the ECACC on May 22, 1996 under Accession No. 96052170.

12. The hybridoma cell line deposited at the ECACC on May 22, 1996 under Accession No. 96052168.

9. A pharmaceutical composition for the prevention and/or treatment of HBV infections comprising as active ingredient an antibody in accordance with Claim 5 and/or 6 together with a pharmaceutically acceptable carrier.

10. A method for the treatment of HBV infections comprising administering to an individual in need a therapeutically effective amount of antibodies according to Claim 5 and/or 6.

11. A method for the prevention of HBV infections comprising administering to an individual an antibody in accordance with Claim 5 and/or 6 to prevent further infection of the treated individual with HBV.

12. A method for the diagnosis of HBV infections in a body fluid sample comprising:

(a) contacting said sample with an antibody of any of Claim 5 or 6 under conditions enabling the formation of antibody-antigen complexes;

(b) determining the level of antibody-antigen complexes formed; a level significantly higher than that formed in a control sample indicating an HBV infection in the tested body fluid sample.

13. Use of an antibody in accordance with claim 5 or 6 in combination with an anti viral agent for the prevention and/or treatment of HBV infection.

14. Use of an antibody in accordance with claim 13 wherein said anti viral agent is selected from the group consisting of: interferons, anti HB polyclonal antibodies, nucleoside analogues and inhibitors of DNA polymerase.

15. A pharmaceutical composition for the prevention and/or treatment of HBV infections comprising as an active ingredient at least one antibody in accordance

Sub B8 cont [with claim 5 or 6 in combination with at least one other active ingredient being an anti viral agent.

8 16. A pharmaceutical composition according to claim ~~15~~ ⁷ wherein the anti viral agent is selected from the group consisting of: interferons, anti HB polyclonal antibodies, nucleoside analogues and inhibitors of DNA polymerase.

Sub B7 [17. A method for the prevention and/or treatment of HBV infections comprising administering to an individual in need a therapeutically effective amount of a pharmaceutical composition according to any one of claims 9, 15 or 16.

18. Use of an antibody in accordance with claim 5 or 6 for the manufacture of a ~~B~~ pharmaceutical composition for the prevention and/or treatment of HBV infections.

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